

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
9 August 2001 (09.08.2001)

PCT

(10) International Publication Number
WO 01/56633 A3

(51) International Patent Classification⁷: A61M 5/168,
5/172, 5/142, B81B 1/00, 3/00

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(21) International Application Number: PCT/US01/03467

(22) International Filing Date: 2 February 2001 (02.02.2001)

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(25) Filing Language: English

(26) Publication Language: English

(81) Designated State (national): DE.

(30) Priority Data:
60/179,924 3 February 2000 (03.02.2000) US

Published:
— with international search report

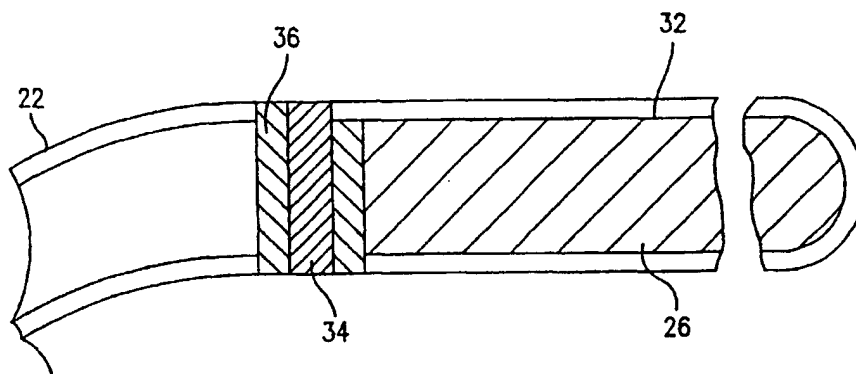
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(88) Date of publication of the international search report:
14 February 2002

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: SINGLE-USE THERAPEUTIC SUBSTANCE DELIVERY DEVICE WITH INFUSION RATE CONTROL



(57) Abstract: The single-use device has a Micro Electro Mechanical system (MEMS) flow restriction (34) with a variable infusion rate. The MEMS flow restriction is fluidly coupled to a reservoir outlet (36) to receive therapeutic substance (26) dispensed from the single-use reservoir (32) at the reservoir rate and restrict the therapeutic substance flow to a desired infusion rate. The single-use reservoir is configured for controlled collapse to dispense therapeutic substance from the reservoir at a reservoir rate through a reservoir outlet. The therapeutic substance delivery device can also be configured as a shrink polymer delivery device. A flow restriction is fluidly coupled to the shrink polymer reservoir outlet to receive therapeutic substance dispensed from the reservoir at the reservoir rate and restrict the therapeutic substance flow to an infusion rate.

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INTERNATIONAL SEARCH REPORT

Inter nal Application No
PCT/US 01/03467

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61M5/168 A61M5/172 A61M5/142 B81B1/00 B81B3/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61M B81B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 772 263 A (DORMAN FRANK D ET AL) 20 September 1988 (1988-09-20) column 1, line 1 -column 3, line 35 column 5, line 38 -column 6, line 28 ---	1-3,19
X	US 5 368 588 A (BETTINGER DAVID S) 29 November 1994 (1994-11-29) cited in the application	19
A	the whole document ---	1-3,5
X	US 4 447 224 A (DECANT JR LEONARD J ET AL) 8 May 1984 (1984-05-08)	19
A	abstract ---	1-4
A	US 5 820 589 A (MCMULLEN RAYMOND F ET AL) 13 October 1998 (1998-10-13)	1-4,19
A	the whole document ---	1-4
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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"8" document member of the same patent family

Date of the actual completion of the international search

7 June 2001

Date of mailing of the international search report

29.08.01

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INTERNATIONAL SEARCH REPORT

International Application No

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 951 916 A (MEDTRONIC INC) 27 October 1999 (1999-10-27) abstract ---	1,19
A	US 5 702 618 A (SAASKI ELRIC W ET AL) 30 December 1997 (1997-12-30) cited in the application abstract; figure 16 ---	1
A	WO 98 23869 A (KLUGE STEFAN ;FRAUNHOFER GES FORSCHUNG (DE)) 4 June 1998 (1998-06-04) abstract; figure 5 ---	1
A	EP 0 892 419 A (TRW INC) 20 January 1999 (1999-01-20) abstract ---	1
A	US 5 897 530 A (JACKSON ROGER W) 27 April 1999 (1999-04-27) column 1, line 15-17 -----	6

INTERNATIONAL SEARCH REPORT

national application No.
PCT/US 01/03467

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 20-24, 36-37
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-6, 19

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

1. Claims: 1-6 , 19

Infusion delivery device with collapsible reservoir for dispensing a therapeutic substance, flow restriction means (MEMS) and delivery means.

2. Claims: 7-18

Shrink polymer delivery device comprising shrink polymer reservoir to dispensing a therapeutic substance and flow restriction coupled to the reservoir outlet

3. Claims: 25-35

MEMS variable flow restriction comprising substrate , passive power source, control electronics, actuator, valve, and means to perform flow restriction.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

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